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Claims

I. Process for preparing a compound of the formula I

in crystalline form, with defined particle size, comprising the steps of

- a) preparation of a solution of the compound of the formula I in a suitable water-miscible organic solvent;
- b) adding the solution obtained as In a) to water and
- isolating the precipitate of the compound of the formula I which is formed.
- Process according to Claim 1, characterized in that the suitable water-miscible organic solvent is an alcohol.
- Process according to Claim 2, characterized in that the alcohol is selected from the group of methanol, ethanol, N-propanol and Isopropanol or mixtures in any mixing ratio thereof.
- 4. Process according to Claim 3, characterized in that ethanol is involved.
- Process according to Claim 1, characterized in that acetone, tetrahydrofuran or dimethylformamide is involved.
- 6. Process according to Claim 1, characterized in that the temperature of the suitable water-miscible organic solvent is in the range from 15°C to 10°C below the boiling point of the solvent.
- 7. Process according to Claim 6, characterized in that the temperature of the suitable water-miscible organic solvent corresponds to the room temperature at which the process is carried out.

- Process according to Claim 1, characterized in that the temperature of the water is from 10 to 50 °C.
- 9. Process according to Claim 7, characterized in that the temperature of the water corresponds to the room temperature at which the process is carried out.
- Process according to Claim 1, characterized in that the compound of the formula I has the chemical name 16,17-[(cyclohexylmethylene)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-diene-3,20-dione [11beta, 16alpha (R,S)].
- 11. Process according to Claim 1, characterized in that the compound of the formula I is substantially in the form of the R epimer.
- 12. Process according to Claim 11, characterized in that the proportion of R epimer in the compound of the formula I is more than 95%.
- 13. Process according to Claim 11, characterized in that ciclesonide is involved.
- Process according to Claim 1, characterized in that the precipitate obtained after step c) is subsequently dried.
- 15. Process for preparing a compound of the formula I according to Claim 1 in crystalline form with defined particle size, comprising the steps of
 - a) preparing a compound of the formula I by acylation of a compound of the formula II

with a sultable acylating agent;

 crystallizing the compound of the formula I obtained in a) by adding water to a solution of the compound in a suitable water-miscible organic solvent or heating a suspension of the WO 2004/085460 PCT/EP2004/050373

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compound of the formula I in a mixture of a suitable water-miscible organic solvent and water,

- removing the resulting R epimer-enriched precipitate of the compound of the formula I from the water/solvent mixture;
- d) If desired repeating step b);
- preparing a solution of the compound obtained in c) in a suitable water-miscible organic solvent:
- f) adding the solution obtained as in e) to water and
- g) isolating the precipitate which has been formed of the compound of the formula i.
- Process according to Claim 1, where the particle size is characterized by an X_∞ of less than or equal to 10.
- 17. Process according to Claim 16, where the particle size is characterized by an X_m of in the range from 1.8 to 2.0..
- Process according to Claim 15, where the organic solvents used in steps b) and e) are the same solvents.
- Compound of the formula I obtainable according to Claim 1 without further micronization step, where the compound is in inhalable form.
- Compound according to Claim 19, where the particle size of the compound of the formula I has an X_α in the range from 1.8 to 2.0.
- 21. Compound according to Claims 19 or 20, which compound is not in micronized form.
- 22. Crystalline ciclesonide with a particle size characterized by an X₀ of less than or equal to 10.
- 23. Crystalline ciclesonide with a particle size characterized by an X_o of in the range from 1.8 to 2.0.
- 24. Crystalline ciclesonide according to Claims 22 or 23, which ciclesonide is not in micronized form.
- 25. Pharmaceutical composition comprising a compound according to Claims 19 to 24, which compound is present as solid particles together with pharmaceutically acceptable exciplents.
- Pharmaceutical composition according to claim 25, which is an aqueous suspension of the compound.

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27. Pharmaceutical composition according to claim 25, which is a dry powder.